UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,791	11/10/2003	Kenneth Chien	6627-P9025D	5197

25225 7590 05/11/2005

MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,791	CHIEN ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-5 drawn to a method of inducing phospholamban deficiency.

II. Claims 6-9, drawn to a mixture of a first peptide and a second peptide.

III. Claims 10-11, drawn to a compound in which a first peptide and a second peptide are covalently bonded together; or else a compound in which a first peptide and a second peptide are both covalently bonded to another compound (e.g., polylysine).

IV. Claims 12-17, drawn to a method of inhibiting PLB-SERCA 2a interaction.

The claimed inventions are distinct.

Groups {II, III} and I are not related as product and process of use. On the other hand, it may be the case that the compounds and mixtures of Groups II and III can be used to "induce phospholamban deficiency". In the event that either of Groups II or III is elected, and claims found allowable, applicants may have rejoined claims that are drawn to a method of using the allowable compounds/ mixtures of compounds.

In the event that Group I is elected, and the claims are found to be allowable without the introduction of any limitations, it may also turn out to be the case that Group IV will be novel. And if the Group I claims are found to be allowable only after limitations have been introduced, it may become appropriate to revisit the matter of restriction between Groups I and IV, provided that applicants are

willing to introduce the same limitations into Group IV that have been introduced into Group I.

Inventions III and II are related as combination/subcombination, or as final product/ intermediate. In the event that Group II is elected, and claims therein found allowable, it is likely to be the case that novelty would accrue to Group III (the reverse is not true, however). Accordingly, in the event that Group II is elected, and claims therein found allowable, it would become appropriate to revisit the matter of restriction between Groups II and III.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group I is chosen for initial examination, election of one of the following species (or subgenera) is required:

a1) the objective of the method is to induce a deficiency in phosphorylated phospholambin;

b1) the objective of the method is to induce a deficiency in unphosphorylated phospholambin;

c1) the objective of the method is to induce a deficiency in phosphorylated phospholambin as well as in unphosphorylated phospholambin.

Additionally, in the event that Group I is chosen for initial examination, election of one of the following species (or subgenera) is required:

a2) the objective of the method is achieved by administering a single, pure compound to a subject in need thereof;

b2) a viral vector is administered, wherein the viral vector contains a gene that encodes an agent which is effective to induce phospholamban deficiency

c2) a composition is administered, wherein the composition consists of two or more compounds, with the proviso that the composition excludes viruses;

d2) method of inducing phospholamban deficiency which is achieved without administering any compounds to a subject afflicted with, or at risk of, heart failure, and which method is achieved without administering any compositions to the subject, and without administering any viral vectors to the subject.

- In the event that a single, pure compound is administered, what exactly is the compound? All atoms in the molecule should be accounted for. Note that, for example, "antisense PLB" would constitute an incomplete response, as this is not a fully defined molecule.

- In the event that a viral vector is administered, which virus is being used, and what peptide or polynucleotide is encoded therein?

- In the event that a composition is administered, what compounds are present?

- In the event that a method for treatment of heart failure is elected which excludes administration of compounds, compositions, and viral vectors, what exactly is the elected method?

. . . .

In the event that Group II is chosen for initial examination, what is the sequence of the first peptide, and what is the sequence of the second peptide?

. . . .

In the event that Group III is chosen for initial examination, what is the structure of the conjugate? Are the two peptides bonded directly to one another, and if so, at what point? Are the first and second peptides bonded to a third molecule, and if so, at what site(s)...?

. . . .

In the event that Group IV is chosen for initial examination, election of one of the following species (or subgenera) is required:

a) the method is achieved by administering a single, pure compound;

b) a viral vector is administered, wherein the viral vector contains a gene that encodes an agent which is effective to inhibit PLB / SERCA2a interaction;

c) A composition is administered, wherein the composition consists of two or more compounds, with the proviso that the composition excludes viruses;

d) the method of inhibiting PLB / SERCA2a interaction is achieved without administering any compounds to a subject afflicted with, or at risk of, heart failure, and which method is achieved without administering any compositions to the subject, and without administering any viral vectors to the subject.

- In the event that a single, pure compound is administered, what exactly is the compound? All atoms in the molecule should be accounted for. Note that, for example, "antisense PLB" would constitute an incomplete response, as this is not a fully defined molecule.

- In the event that a viral vector is administered, which virus is being used, and what peptide or polynucleotide is encoded therein?

- In the event that a composition is administered, what compounds are present?

- In the event that a method for treatment of heart failure is elected which excludes administration of compounds, compositions, and viral vectors, what exactly is the elected method?

. . . .

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. ∋103 of the other invention.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600